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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/251,638	02/17/1999	HENRY DANIELL	922.6641P	3456
35811	7590	08/18/2005	EXAMINER	
IP GROUP OF DLA PIPER RUDNICK GRAY CARY US LLP 1650 MARKET ST SUITE 4900 PHILADELPHIA, PA 19103			KUBELIK, ANNE R	
		ART UNIT		PAPER NUMBER
		1638		

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/251,638	DANIELL, HENRY
Examiner	Art Unit	
Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 June 2005.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-5 and 8-12 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3-5 and 8-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date: _____	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on ~~7 Oct 2005~~ has been entered.

2. Claims 1, 3-5 and 8-12 are pending.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The amendment filed 3 June 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendments to paragraphs 10.2, 10.4, 10.41, 10.42, 10.4.3 and 18 are new matter. Applicant is required to cancel the new matter or provide support in the form of submission of the references from which they were taken in the reply to this Office Action.

5. The objection to claim 10 to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of applicant's amendment of the claim.

6. The objection to claims 4-5 is withdrawn in light of applicant's amendment of the claims.

7. The rejection of claims 1, 3-5 and 8-10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of applicant's amendment of the claims.

*Claim Objections*

8. Claim 12 objected to for starting with an improper article.

*Claim Rejections - 35 USC § 112*

9. Claims 1, 3-5 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 2 April 2004, as applied to claims 1, 3-5 and 8-10. Applicant's arguments filed 3 June 2005 have been fully considered but they are not persuasive.

The claims are broadly drawn to multitude of expression cassettes comprising nucleic acids that comprise a synthetic coding sequence encoding a pentapeptide that is repeated at least once and cotton plants comprising any of a multitude of nucleic acids that comprise a synthetic coding sequence encoding any pentapeptide that is repeated at least once.

The instant specification, however, only provides guidance for a nucleic acid encoding GVGVPVGFPGEFPVGVPVGFGFP (paragraph 10.3), which comprises GVGVP twice.

The specification does not teach how to distinguish synthetic coding sequences from nonsynthetic ones, and does not teach any pentapeptides to be other than GVGVP or VPGVG.

The specification states that one method (particle bombardment) of cotton transformation requires undue experimentation to carry out (pg 6), and the other (Agrobacterium-mediated) can only be carried out on certain cotton cultivars. The specification fails to teach these cultivars.

Given the claim breadth and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids that comprise a synthetic coding sequence encoding any pentapeptide that is repeated at least once and cotton plants comprising them.

Applicant urges that one of skill in the art would understand what is meant by synthetic, citing Webster's, and using synthetic oligonucleotides is well known in the art, citing, McPherson and Zhang (response pg 13).

This is not found persuasive. The rejection is not an indefiniteness rejection; it is an enablement rejection. The specification does not teach how to distinguish synthetic coding sequences from nonsynthetic ones; that is it does not teach how to distinguish infringing compounds from noninfringing ones. Webster's, McPherson and Zhang could not be considered because they were not sent.

Applicant urges that the inventor has categorized GVGVP in a multitude of different systems and expressed it as a pentapeptide of 20 and 251 repeats, and repeats of 121 were known in the art; other examples are detailed in the specification, citing papers incorporated by references into the specification (response pg 14-15).

This is not found persuasive because the specification does not teach a nucleic acid encoding repeats of GVGVP of other than 20, 121 or 250, nor does it teach a nucleic acid encoding repeats of any other pentapeptide. The papers could not be considered because they were not sent.

Applicant urges that a cultivar useful for regeneration after Agrobacterium-mediated transformation was incorporated by reference into the specification (response pg 15).

This is not found persuasive because that paper could not be considered because it was not sent.

10. Claims 1, 3-5 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 2 April 2004, as applied to claims 1, 3-5 and 8-10. Applicant's arguments filed 3 June 2005 have been fully considered but they are not persuasive.

The claims are broadly drawn to a multitude of nucleic acids that comprise a synthetic coding sequence encoding a pentapeptide that is repeated at least once. In contrast, the specification describes no nucleic acid encompassed by the claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

The specification does not describe the structural features that distinguish synthetic sequences from nonsynthetic ones.

Hence, Applicant has not, in fact, described nucleic acids that comprise a synthetic coding sequence encoding a pentapeptide that is repeated at least once, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

Applicant urges that those skilled in the art knew well the difference between synthetic and non-synthetic sequences (response pg 16).

This is not found persuasive. What is that difference? What are the structural features that distinguish synthetic from nonsynthetic sequences?

11. Claims 1, 3, 5 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 2 April 2004. Applicant's arguments filed 3 June 2005 have been fully considered but they are not persuasive.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase ““The transgenic cotton plant of claim 1, wherein said gene encodes between 20-251 repeats of the amino acid sequence Gly-Val-Gly-Val-Pro (SEQ ID NO:2)”. Thus, such phrases constitute NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrases or to cancel the new matter.

Applicant urges that support for 121 repeats of GVGVP is found on pg 2 of the provisional application (response pg 16).

This is not found persuasive. There is no support for 21-99 or 101-249 repeats.

12. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Claim 12 is indefinite in its recitation of “cotton plant ... where the pentapeptide is repeated in multiples of ten”. It is not clear if applicant means that the pentapeptide is repeated

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10, 20, or 30 etc times or if the pentapeptide is repeated both 10 and 20 times, for example, in the same plant.

13. Claims 1, 3-5 and 8-12 are free of the prior art, given the failure of the prior art to teach a cotton plant transformed with a gene or coding sequence that encodes a protein comprises at least one pentapeptide that is repeated at least once, wherein the gene or coding sequence does not occur in nature and given the failure of the prior art to teach an expression cassette for transformation of such plants, wherein the cassette comprises a fiber-specific promoter.

### *Conclusion*

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.  
August 11, 2005



ANNE KUBELIK, PH.D.  
PRIMARY EXAMINER